

References

- Avril N, Dose J, Janicke F, Sense S, Ziegler S, Laubenbacher C, Romer W, Pache H, Herz M, Allgayer B, Nathrath W, Graeff H, Schwaiger M. Metabolic characterization of breast tumors with positron emission tomography using F-18 fluorodeoxyglucose. *J Clin Oncol* 1996;14:1848-57.
- Bury T, Dowlati A, Paulus P, Corhay JL, Hustinx R, Ghaye B, Radermecker M, Rigo R. Whole-body 18-FDG positron emission tomography staging of non-small cell lung cancer. *Eur Respir J* 1997;10:2529-2534.
- Carr R, Barrington SF, Madan B, O'Doherty MJ, Saunders CAB, van der Walt J, Timothy AR. Detection of lymphoma in bone marrow by whole-body positron emission tomography. *Blood* 1998;91:3340-46.
- Delbeke D, Martin WH, Sandler MP, Chapman W, Wright Jr K, Pinson W. Evaluation of benign vs malignant hepatic lesions with positron emission tomography. *Arch Surg* 1998;133:510-516.
- Dietlein M, Scheidhauer K, Voth E, Theissen P, Schicha H. Fluorine-18 fluorodeoxyglucose positron emission tomography and iodine-131 whole-body scintigraphy in the follow-up of differentiated thyroid cancer. *Eur J Nucl Med* 1997;24:1342-48.
- Friess H, Langhans J, Ebert M, Beger HG, Stollfuss J, Reske SN, Buchler MW. Diagnosis of pancreatic cancer by 2[18-F]-fluoro-2-deoxy-D-glucose positron emission tomography. *Gut* 1995;36:771-777.
- Gupta NC, Maloof J, and Gunel E. Probability of malignancy in solitary pulmonary nodules using fluorine-18-FDG and PET. *J Nucl Med* 1996;37:943-948.
- Holder Jr. W, White RL, Zuger JH, Easton Jr. EJ, Greene FL. Effectiveness of positron emission tomography for the detection of melanoma metastases. *Annals of Surg* 1998;227:764-771.

Lowe VJ, Fletcher JW, Gobar L, Lawson M, Kirchner P, Valk P, Karis J, Hubner K, Delbeke D, Heiberg EV, Patz EF, Coleman RE. Prospective investigation of positron emission tomography in lung nodules. *J Clin Oncol* 1998;16:1075-1084.

Lowe VJ, Hoffman JM, DeLong DM, Patz Jr. EF, Coleman RE. Semiquantitative and visual analysis of FDG-PET images in pulmonary abnormalities. *J Nucl Med* 1994;35:1771-1776.

Meyer GJ, Waters SL, Coenen HH, Luxen A, Maziere B, Langstrom B. PET radiopharmaceuticals in Europe: current use and data relevant for the formation of summaries of product characterizatics (SpCs). *Eur J Nucl Med* 1995;22:1420-32.

Moog F, Bangerter M, Kotzerke J, Guhlmann A, Frickhofen N, Reske SN. 18-F-fluorodeoxyglucose-positron emission tomography as a new approach to detect lymphomatous bone marrow. *J Clin Oncol* 1998;16:603-9.

Sazon DA, Santiago SM, Soo Hoo GW, Khonsary A, Brown C, Mandelkern M, Blahd W, and Williams AJ. Fluorodeoxyglucose-positron emission tomography in the detection and staging of lung cancer. *Am J Respir Crit Care Med.* 1996;153:417-21.

Schepers C, Penninckx R, De Vadder N, Merckx E, Mortelmans L, Bormans G, Marchal G, Filez L, Aerts R. Contribution of PET in the diagnosis of recurrent colorectal cancer: comparison with conventional imaging. *Euro J of Surgical Oncology* 1995;21:517-522.

Silberstein EB, Ryan J, and the Pharmacopeia Committee of the Society of Nuclear Medicine. Prevalence of adverse reactions in nuclear medicine. *J Nucl Med* 1996;37:185-92.

Silberstein EB and the Pharmacopeia Committee of the Society of Nuclear Medicine. Prevalence of adverse reactions to positron emitting radiopharmaceuticals in nuclear medicine. *J Nucl Med* 1998;39:2190-2.

Utech C, Young CS, Winter PF. Prospective evaluation of fluorine-18 fluorodeoxyglucose positron emission tomography in breast cancer for staging of the axilla related to surgery and immunocytochemistry. *Eur J Nucl Med* 1996;23:1588-93.

Valk PE, Pounds TR, Hopkins DM, Haseman MK, Hofer GA, Greiss HB, Myers RW, Lutrin CL. Staging Non-small cell lung cancer by whole-body positron emission tomographic imaging. Ann Thorac Surg 1995;60:1573-82.

Vansteenkiste JF, Stroobants SG, De Leyn PR, Dupont PJ, Bogaert J., Maes A, Deneffe GJ, Nackaerts KL, Verschakelen JA, Lerut TE, Mortelmans LA, Demedts MG. Lymph node staging in non-small cell lung cancer with FDG-PET scan: a prospective study of 690 lymph node stations from 68 patients. J Clin Oncol 1998;16:2142-2149.

**THIS DOCUMENT IS NOT INCLUDED BECAUSE IT
CONTAINS COPYWRITED MATERIALS**

**DOCKET
98D-0266**

ON

SECTION 121 POSITRON EMISSION TOMOGRAPHY (PET) FDAMA

THIS MATERIAL MAY BE OBTAINED BY

VISITING THE PUBLIC ROOM AT

**DOCKETS MANAGEMENT BRANCH
FOOD & DRUG ADMINISTRATION
5630 FISHERS LANE, ROOM 1043
ROCKVILLE, MD 20852**